PTO/SB/21 (08-00) Approved for use through 10/31/2002. OMB 0651-0031 Heast type a plus sign (+) inside this box ──> U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. 10/718.976 **Application Number** TRANSMITTAL November 20, 2003 Filing Date **FORM** Syed F.A. Hossainy **First Named Inventor** 1615 (to be used for all correspondence after initial filing) **Group Art Unit** Unassigned **Examiner Name** Total Number of Pages in This Submission 13 50623.317 Attorney Docket No. (excluding references) ENCLOSURES (check all that apply) After Allowance Communication to Deposit Account Authorization **Assignment Papers** (for an Application) 07-1850 Group Appeal Communication to Board of Postage Paid Return Postcard Formal Drawing(s) Appeals and Interferences Appeal Communication to Group Response to Office Action Licensing-related Papers (Appeal Notice, Brief, Reply Brief) Petition Proprietary Information After Final Petition to Convert to a Submission of Formal Drawings (in Affidavits/declaration(s) Provisional Application duplicate) Power of Attorney, Revocation Petition for Extension of Time (____ Other Enclosure(s) Change of Correspondence Address (please identify below): month) (in duplicate) Terminal Disclaimer Amendment Transmittal Letter (in duplicate) Request for Refund Information Disclosure Statement with Form PTO-1449 and 204 CD, Number of CD(s) References Request for Continued Examination Remarks (RCE) Transmittal Express Mail Label No. Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Squire, Sanders & Dempsey L.L.P. Victor Repkin, Jr., Reg. No. 45,039 Individual name Signature Date March 4, 2004 CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: March 4, 2004 Typed or printed name Rebecca M. Klits '

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date

March 4, 2004

Signature

IN THE CONTROL STATES PATENT AND TRADEMARK OFFICE

In reApplication of:

Examiner:

Unassigned

Syed F.A. Hossainy et al.

Serial No.

10/718,976

Art Unit:

1615

Filed:

November 20, 2003

Title:

Coatings For Implantable Devices Comprising Polymers Of Lactic Acid

And Methods For Fabricating The Same

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§1.97-1.98

Dear Examiner:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §§1.97-1.98, Applicants hereby notify the U.S. Patent and Trademark Office of the references listed on the attached Form PTO-1449. According to a Notice signed July 11, 2003, the U.S. Patent and Trademark Office has waived the requirement under 37 C.F.R. § 1.98(a)(2)(i) for all patent applications filed after June 30, 2003. *See*, 1276 Off. Gaz. Pat. Office 55. Since this patent application was filed after June 30, 2003, Applicants have not provided copies of the cited U.S. patents or the U.S. Patent Application Publications. Copies of the cited foreign patent documents and non-patent literature have been submitted herewith.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants reserve the right to dispute the listed documents as prior art during examination. Furthermore, Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application. The submission of this Information Disclosure Statement is not to be construed as a representation that a search has been made or that no other material information may exist.

The Examiner is requested to initial the enclosed Form PTO-1449 and return a copy thereof to the undersigned.

The present Information Disclosure Statement is being filed before receiving the first Office Action. Therefore, no certification under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required. However, the Commissioner is authorized to charge any deficiencies or other amounts due to Deposit Account No. 07-1850.

Date: March 4, 2004

SQUIRE, SANDERS & DEMPSEY L.L.P. One Maritime Plaza, Suite 300 San Francisco, CA 94111 Telephone (415) 954-0200 Facsimile (415) 393-9887 Respectfully submitted,

Victor Repkin

Attorney for Applicant

Reg. No. 45,039

FORM PTO-1449 (Modified)

in an Application (Use several sheets if necessary)

groved for use through 10/31/2002 YOMFORMATION DISCLOSURE CITATION

US DEPARTMENT OF COMMERCE US Patent and Trademark Office

Docket No. Application No. 50623.317 10/718,976

Applicant

Syed F.A. Hossainy et al.

427

424

623

424

623

Berg et al.

Helmus et al.

Haimovich et al.

Eury et al.

Fearnot et al.

2.30

426

1

423

1

4/26/93

6/7/95

9/16/94

3/30/95

6/7/95

Filing Date

November 20, 2003

Group Art Unit 1615

	<u> </u>		November 20, 2003 1615					
ACG	<i>y</i>		U.S. PATI	TENT DOCUMENTS				
Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date i Appropriate	
	A1	4,329,383	5/11/82	Joh	428	36	7/21/80	
	A2	4,733,665	3/29/88	Palmaz	128	343	11/7/85	
	А3	4,800,882	1/31/89	Gianturco	128	343	3/13/87	
	A4 ·	4,882,168	11/21/89	Casey et al.	424	468	9/5/86	
,	A5	4,886,062	12/12/89	Wiktor	128	343	10/19/87	
	A6	4,941,870	7/17/90	Okada et al.	600	36	12/30/88	
	A7	4,977,901	12/18/90	Ofstead	128	772	4/6/90	
	A8	5,112,457	5/12/92	Marchant	204	165	7/23/90	
	A9	5,165,919	11/24/92	Sasaki et al.	424	488	9/26/90	
	A10	5,272,012	12/21/93	Opolski	428	423.1	1/29/92	
· i	A11	5,292,516	3/8/94	Viegas et al.	424	423	11/8/91	
	A12	5,298,260	3/29/94	Viegas et al.	424	486	6/9/92	
	A13	5,300,295	4/5/94	Viegas et al.	424	427	9/13/91	
	A14	5,306,501	4/26/94	Viegas et al.	424	423	11/8/91	
	A15	5,328,471	7/12/94	Slepian	604	101	8/4/93	
	A16	5,330,768	7/19/94	Park et al.	424	501	7/5/91	
	A17	5,380,299	1/10/95	Fearnot et al.	604	265	8/30/93	
	A18	5,417,981	5/23/95	Endo et al.	424	486	4/28/93	
	A19	5,447,724	9/5/95	Helmus et al.	424	426	11/15/93	
	A20	5,455,040	10/3/95	Marchant	424	426	11/19/92	
	A21	5,462,990	10/31/95	Hubbell et al.	525	54.1	10/5/93	

11/7/95

10/29/96

11/26/96

2/25/97

3/11/97

A22

A23

A24

A25

A26

5,464,650

5,569,463

5,578,073

5,605,696

5,609,629

	1		1 1 1 1 1 1 1		T		
	A27	5,624,411	4/29/97	Tuch	604	265	6/7/95
	A28	5,628,730	5/13/97	Shapland et al.	604	21	7/18/94
	A29	5,649,977	7/22/97	Campbell	623	1	9/22/94
	A30	5,658,995	8/19/97	Kohn et al.	525	432	11/27/95
	A31	5,667,767	9/16/97	Greff et al.	424	9.411	7/27/95
	A32	5,670,558	9/23/97	Onishi et al.	523	112	7/6/95
	A33	5,679,400	10/21/97	Tuch	427	2.14	6/7/95
	A34	5,700,286	12/23/97	Tartaglia et al.	623	1	8/22/96
	A35	5,702,754	12/30/97	Zhong	427	2.12	2/22/95
	A36	5,716,981	2/10/98	Hunter et al.	514	449	6/7/95
	A37	5,735,897	4/7/98	Buirge	623	12	1/2/97
	A38	5,746,998	5/5/98	Torchilin et al.	424	9.4	8/8/96
	A39	5,776,184	7/7/98	Tuch	623	1	10/9/96
	A40	5,788,979	8/4/98	Alt et al.	424	426	2/10/97
	A41	5,800,392	9/1/98	Racchini	604	96	5/8/96
	A42	5,820,917	10/13/98	Tuch	427	2.1	6/7/95
	A43	5,824,048	10/20/98	Tuch	623	1	10/9/96
	A44	5,824,049	10/20/98	Ragheb et al.	623	1	10/31/96
	A45	5,830,178	11/3/98	Jones et al.	604	49	10/11/96
	A46	5,837,008	11/17/98	Berg et al.	623	1	4/27/95
	A47	5,837,313	11/17/98	Ding et al.	427	2.21	6/13/96
	A48	5,851,508	12/22/98	Greff et al.	424	9.411	2/14/97
	A49	5,858,746	1/12/99	Hubbell et al.	435	177	1/25/95
	A50	5,865,814	2/2/99	Tuch	· 604	265	8/6/97
	A51	5,869,127	2/9/99	Zhong	427	2.12	6/18/97
	A52	5,873,904	2/23/99	Ragheb et al.	623	1	2/24/97
	A53	5,876,433	3/2/99	Lunn	623	1	5/29/96
, y	A54	5,877,224	3/2/99	Brocchini et al.	514	772.2	7/28/95
	A55	5,925,720	7/20/99	Kataoka et al.	525	523	12/18/97
	A56	5,955,509	9/21/99	Webber et al.	514	772.7	4/23/97
	A57	5,971,954	10/26/99	Conway et al.	604	96	1/29/97
	A58	5,980,928	11/9/99	Terry	424	427	7/29/97

A59	5,980,972	11/9/99	Ding	427	2.24	9/22/97
A60	5,997,517	12/7/99	Whitbourne	604	265	1/27/97
A61	6,010,530	1/4/00	Goicoechea	623	1	2/18/98
 A62	6,015,541	1/18/00	Greff et al.	424	1.25	11/3/97
A63	6,033,582	3/7/00	Lee et al.	216	37	1/16/98
A64	6,042,875	3/28/00	Ding et al.	427	2.24	3/2/99
A65	6,051,648	4/18/00	Rhee et al.	525	54.1	1/13/99
A66	6,051,576	4/18/00	Ashton et al.	514	255	1/29/97
A67	6,056,993	5/2/00	Leidner et al.	427	2.25	4/17/98
A68	6,060,451	5/9/00	DiMaio et al.	514	13	3/20/95
 A69	6,060,518	5/9/00	Kabanov et al.	514	781	8/16/96
A70	6,080,488	6/27/00	Hostettler et al.	428	423.3	3/24/98
 A71	6,096,070	8/1/00	Ragheb et al.	623	1	5/16/96
A72	6,099,562	8/8/00	Ding et al.	623	1.46	12/22/97
A73	6,110,188	8/29/00	Narciso, Jr.	606	153	3/9/98
 A74	6,110,483	8/29/00	Whitbourne et al.	424	423	6/23/97
 A75	6,113,629	9/5/00	Ken	623	1.1	5/1/98
A76	6,120,536	9/19/00	Ding et al.	623	1.43	6/13/96
A77	6,120,904	9/19/00	Hostettler et al.	428	423.3	5/24/99
 A78	6,121,027	9/19/00	Clapper et al.	435	180	8/15/97
 A79	6,129,761	10/10/00	Hubbell	623	11	6/7/95
A80	6,153,252	11/28/00	Hossainy et al.	427	2.3	4/19/99
A81	6,165,212	12/26/00	Dereume et al.	623	1.13	6/28/99
A82	6,203,551	3/20/01	Wu	606	108	10/4/99
A83	6,231,600	5/15/01	Zhong	623	1.42	5/26/99
A84	6,240,616	6/5/01	Yan	29	527.2	4/15/97
A85	6,245,753	6/12/01	Byun et al.	514	56	4/27/99
A86	6,251,136	6/26/01	Guruwaiya et al.	623	1.46	12/8/99
 A87	6,254,632	7/3/01	Wu et al.	623	1.15	9/28/00
A88	6,258,121	7/10/01	Yang et al.	623	1.46	7/2/99
A89	6,283,947	9/4/01	Mirzaee	604	264	7/13/99

A90	6,283,949	9/4/01	Roorda	604	288.02	12/27/99
A91	6,284,305	9/4/01	Ding et al.	427	2.28	5/18/00
A92	6,287,628	9/11/01	Hossainy et al.	427	2.3	9/3/99
 A93	6,299,604	10/9/01	Ragheb et al.	604	265	8/20/99
 A94	6,306,176	10/23/01	Whitbourne	623	23.59	9/21/99
 A95	6,331,313	12/18/01	Wong et al.	424	427	10/22/99
A96	6,335,029	1/1/02	Kamath et al.	424	423	12/3/98
 A97	6,346,110	2/12/02	Wu	606	108	1/3/01
 A98	6,358,556	3/19/02	Ding et al.	427	2.24	1/23/98
A99	6,379,381	4/30/02	Hossainy et al.	623	1.42	9/3/99
A100	6,395,326	5/28/02	Castro et al.	427	2.24	5/31/00
A101	6,419,692	7/16/02	Yang et al.	623	1.15	2/3/99
A102	6,451,373	9/17/02	Hossainy et al.	427	2.25	8/4/00
A103	6,494,862	12/17/02	Ray et al.	604	96.01	12/30/99
A104	6,503,556	1/7/03	Harish et al.	427	2.24	12/28/00
A105	6,503,954	1/7/03	Bhat et al.	514	772.2	7/21/00
A106	6,506,437	1/14/03	Harish et al.	427	2.25	10/17/00
A107	6,527,801	3/4/03	Dutta	623	1.46	4/13/00
A108	6,527,863	3/4/03	Pacetti et al.	118	500	6/29/01
 A109	6,540,776	4/1/03	Sanders Millare et al.	623	1.15	12/28/00
A110	6,544,223	4/8/03	Kokish	604	103.01	1/5/01
A111	6,544,543	4/8/03	Mandrusov et al.	424	422	12/27/00
A112	6,544,582	4/8/03	Yoe	427	2.24	1/5/01
A113	6,555,157	4/29/03	Hossainy	427	2.24	7/25/00
 A114	6,558,733	5/6/03	Hossainy et al.	427	2.24	10/26/00
A115	6,565,659	5/20/03	Pacetti et al.	118	500	6/28/01
 A116	6,572,644	6/3/03	Moein	623	1.11	6/27/01
A117	6,585,765	7/1/03	Hossainy et al.	623	1.45	6/29/00
 A118	6,585,926	7/1/03	Mirzaee	264	400	8/31/00

	A119	6,605,154	8/12/03	Villareal	118	500	5/3	1/01
		U.S. PATE	NT APPLICAT	ION PUBLICATION DOCU	MENTS			
Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	_	Date if opriate
	A120	2001/0018469	8/30/01	Chen et al.	523	121	12/2	8/00
	A121	2001/0037145	11/1/01	Guruwaiya et al.	623	1.15	6/2	1/01
	A122	2002/0077693	6/20/02	Barclay et al.	623	1.13	12/1	9/00
	A123	2002/0091433	7/11/02	Ding et al.	623	1.2	12/1	7/01
	A124	2002/0155212	10/24/02	Hossainy	427	2.25	4/24	4/01
	A125	2003/0065377	4/3/03	Davila et al.	623	1.13	4/30	0/02
	A126	2003/0099712	5/29/03	Jayaraman	424	486	11/2	6/01
			FOREIGN PA	ATENT DOCUMENTS				
Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Trans Yes	lation No
	B1	EP 0 301 856	2/1/89	European				
	B2	EP 0 514 406	11/25/92	European				
	В3	EP 0 604 022	6/29/94	European				
	B4	EP 0 623 354	11/9/94	European				
	B5	EP 0 665 023	8/2/95	European				
	B6	EP 0 701 802	3/20/96	European				
	B7	EP 0 716 836	6/19/96	European				
	B8	EP 0 809 999	12/3/97	European				
	В9	EP 0 832 655	4/1/98	European				
	B10	EP 0 850 651	7/1/98	European		11. 7		
	B11	EP 0 879 595	11/25/98	European				
	B12	EP 0 910 584	4/28/99	European				
<u></u>	B13	EP 0 923 953	6/23/99	European				
	B14	EP 0 953 320	11/3/99	European				
	B15	EP 0 970 711	1/12/00	European				
	B16	EP 0 982 041	3/1/00	European				
	B17	EP 1 273 314	1/8/03	European				
	B18	2001-190687	7/17/01	Japan (Abstract)			Х	
	B19	WO 91/12846	9/5/91	PCT				
	B20	WO 95/10989	4/27/95	PCT				

B21	WO 96/40174	12/19/96	PCT			
B22	WO 97/10011	3/20/97	PCT			
B23	WO 97/45105	12/4/97	PCT			
B24	WO 97/46590	12/11/97	PCT			
B25	WO 98/17331	4/30/98	PCT			
B26	WO 98/36784	8/27/98	PCT			
B27	WO 99/01118	1/14/99	PCT			
B28	WO 99/38546	8/5/99	PCT			
B29	WO 99/63981	12/16/99	PCT			
B30	WO 00/02599	1/20/00	PCT			
B31-	WO 00/12147	3/9/00	PCT			
B32	WO 00/18446	4/6/00	PCT			
B33	WO 00/64506	11/2/00	PCT			
B34	WO 01/01890	1/11/01	PCT			
B35	WO 01/15751	3/8/01	PCT			
B36	WO 01/17577	3/15/01	PCT			
B37	WO 01/45763	6/28/01	PCT			
B38	WO 01/49338	7/12/01	PCT			
B39	WO 01/74414	10/11/01	PCT			
B40	WO 02/03890	1/17/02	PCT			
B41	WO 02/026162	4/4/02	PCT			
B42	WO 02/34311	5/2/02	PCT			
B43	WO 02/056790	7/25/02	PCT			
B44	WO 03/000308	1/3/03	PCT			
B45	WO 03/022323	3/20/03	PCT			
B46	WO 03/028780	4/10/03	PCT			
B47	WO 03/037223	5/8/03	PCT			
B48	WO 03/039612	5/15/03	PCT			
	OTHER DO	CUMENTS (inc	luding Author, Title, Date, Pertinent P	ages, etc.)		
C1			the Dream Stent, Clinica 710:15 (J ht?req=1061848202959, printed 8/			
C2			complications by 30%, Clinica 732 ht?reg=1061847871753, printed 8/),	

СЗ	Anonymous, Rolling Therapeutic Agent Loading Device for Therapeutic Agent Delivery or Coated Stent (Abstract 434009), Res. Disclos. pp. 974-975 (June 2000).
C4	Anonymous, Stenting continues to dominate cardiology, Clinica 720:22 (Sept. 2, 1996), http://www.dialogweb.com/cgi/document?req=1061848017752 , printed 8/25/03 (2 pages).
C5	Aoyagi et al., Preparation of cross-linked aliphatic polyester and application to thermo-responsive material, Journal of Controlled Release 32:87-96 (1994).
 C6	Barath et al., Low Dose of Antitumor Agents Prevents Smooth Muscle Cell Proliferation After Endothelial Injury, JACC 13(2): 252A (Abstract) (Feb. 1989).
C7	Barbucci et al., Coating of commercially available materials with a new heparinizable material, J. Biomed. Mater. Res. 25:1259-1274 (Oct. 1991).
 C8	Chung et al., Inner core segment design for drug delivery control of thermo-responsive polymeric micelles, Journal of Controlled Release 65:93-103 (2000).
C9	Dev et al., Kinetics of Drug Delivery to the Arterial Wall Via Polyurethane-Coated Removable Nitinol Stent: Comparative Study of Two Drugs, Catheterization and Cardiovascular Diagnosis 34:272-278 (1995).
C10	Dichek et al., Seeding of Intravascular Stents with Genetically Engineered Endothelial Cells, Circ. 80(5):1347-1353 (Nov. 1989).
C11	Eigler et al., Local Arterial Wall Drug Delivery from a Polymer Coated Removable Metallic Stent: Kinetics, Distribution, and Bioactivity of Forskolin, JACC, 4A (701-1), Abstract (Feb. 1994).
 C12	Helmus, Overview of Biomedical Materials, MRS Bulletin, pp. 33-38 (Sept. 1991).
C13	Herdeg et al., Antiproliferative Stent Coatings: Taxol and Related Compounds, Semin. Intervent. Cardiol. 3:197-199 (1998).
C14	Inoue et al., An AB block copolymer of oligo(methyl methacrylate) and poly(acrylic acid) for micellar delivery of hydrophobic drugs, Journal of Controlled Release 51:221-229 (1998).
 C15	Kataoka et al., Block copolymer micelles as vehicles for drug delivery, Journal of Controlled Release 24:119-132 (1993).
C16	Levy et al., Strategies For Treating Arterial Restenosis Using Polymeric Controlled Release Implants, Biotechnol. Bioact. Polym. [Proc. Am. Chem. Soc. Symp.], pp. 259-268 (1994).
 C17	Liu et al., <i>Drug release characteristics of unimolecular polymeric micelles</i> , Journal of Controlled Release 68:167-174 (2000).
 C18	Marconi et al., Covalent bonding of heparin to a vinyl copolymer for biomedical applications, Biomaterials 18(12):885-890 (1997).
C19	Matsumaru et al., <i>Embolic Materials For Endovascular Treatment of Cerebral Lesions</i> , J. Biomater. Sci. Polymer Edn 8(7):555-569 (1997).
 C20	Miyazaki et al., Antitumor Effect of Implanted Ethylene-Vinyl Alcohol Copolymer Matrices Containing Anticancer Agents on Ehrlich Ascites Carcinoma and P388 Leukemia in Mice, Chem. Pharm. Bull. 33(6) 2490-2498 (1985).
C21	Miyazawa et al., Effects of Pemirolast and Tranilast on Intimal Thickening After Arterial Injury in the Rat, J. Cardiovasc. Pharmacol., pp. 157-162 (1997).
 C22	Nordrehaug et al., <i>A novel biocompatible coating applied to coronary stents</i> , European Heart Journal 14, p. 321 (P1694), Abstr. Suppl. (1993).
 C23	Ohsawa et al., Preventive Effects of an Antiallergic Drug, Pemirolast Potassium, on Restenosis After Percutaneous Transluminal Coronary Angioplasty, American Heart Journal 136(6):1081-1087 (Dec. 1998).
 C24	Ozaki et al., New Stent Technologies, Progress in Cardiovascular Diseases, Vol. XXXIX(2):129-140 (Sept./Oct. 1996).
C25	Pechar et al., Poly(ethylene glycol) Multiblock Copolymer as a Carrier of Anti-Cancer Drug Doxorubicin, Bioconjucate Chemistry 11(2):131-139 (Mar./Apr. 2000).

EXAMINER		DATE CONSIDERED
	C30	Yokoyama et al., Characterization of physical entrapment and chemical conjugation of adriamycin in polymeric micelles and their design for in vivo delivery to a solid tumor, Journal of Controlled Release 50:79-92 (1998).
	C29	Wilensky et al., Methods and Devices for Local Drug Delivery in Coronary and Peripheral Arteries, Trends Cardiovasc. Med. 3(5):163-170 (1993).
	C28	van Beusekom et al., Coronary stent coatings, Coronary Artery Disease 5(7):590-596 (July 1994).
	C27	Shigeno, Prevention of Cerebrovascular Spasm By Bosentan, Novel Endothelin Receptor, Chemical Abstract 125:212307 (1996).
·	C26	Peng et al., Role of polymers in improving the results of stenting in coronary arteries, Biomaterials 17:685-694 (1996).

EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.